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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,196

02/23/2006

Nils Holmstrom

P05,0038

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03/13/2009

SCHIFF HARDIN, LLP  
PATENT DEPARTMENT  
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EXAMINER

DANEGA, RENEE A

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

03/13/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,196	<b>Applicant(s)</b> HOLMSTROM ET AL.	
	<b>Examiner</b> Renee Danega	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 18 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulligan et al. (US 6438408) in view of Hunt ("Atrial Systolic Function in Left Heart Failure").

- Regarding claim 18, Mulligan teaches a congestive heart failure monitor comprising an impedance-measuring unit having two electrodes configured to measure an impedance signal in a patient that directly indicates and has a signal characteristic representing a change in volume of the left atrium of the heart of the patient (column 6, lines 10-43). Mulligan teaches an analyzing unit that is supplied with an impedance signal during the cardiac cycle and determines the minimum and maximum of the signal to detect congestive heart failure but doesn't expressly teach taking a quotient (column 16, lines 28-65). However, Hunt teaches the atrial ejection fraction or ratio of minimum to maximum volumes to be a measure associated with heart failure (Introduction). It would have been obvious in view of Hunt to enable the analyzing unit to calculate atrial ejection fraction from the impedance signal characterizing

the change in heart volume in Mulligan in order to more accurately characterize congestive heart failure.

- Regarding claims 26-27, Mulligan teaches the electrodes are configured for implantation into the right atrium, left atrium, and left ventricles of the heart (column 11, lines 10-15).
- Regarding claim 28, Mulligan teaches the monitor having a housing adapted for implantation with measuring and analyzing units wherein the first of the electrodes is adapted for implantation into the left atrium of the heart (17) and second of the electrodes is formed by an exterior of the housing (51) (50) (Figures 1, 2)
- Regarding claim 29, Mulligan teaches the electrodes are configured for implantation respective in the left atrium of said heart and the left ventricle of said heart proceeding in a coronary vein (48) (column 11, lines 10-15) (Figure 1).

3. Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulligan modified by Hunt as applied to claim 18 above, and further in view of Pitts Crick et al. (US 6104949).

- Regarding claims 19, 21- 22, and 24, Mulligan modified by Hunt doesn't expressly teach the analysis unit to include an averaging unit capable of forming a floating average impedance value. However, Pitts Crick teaches an averaging unit for performing a floating average of impedances in order to create a baseline for determining congestive heart failure (column 5,

lines 23-57). It would have been obvious in view of Pitts Crick to form an average in Mulligan modified by Hunt in order to account for postural changes in determining congestive heart failure.

- Regarding claims 20 and 23, Mulligan teaches the analysis unit to comprise a comparator capable of comparing an average with a predetermined value (clm 6f) (106) (Figure 2).
- Regarding claim 25, Mulligan modified by Hunt doesn't expressly teach averaging units and comparators for quotient and impedance values for first and second results. However, Pitts Crick teaches two comparators in the determination of congestive heart failure (5-6) (5-8). It would have been obvious in view of Pitts Crick to provide multiple comparators in Mulligan modified by Hunt to allow for more than one indicator of congestive heart failure to be analyzed.

4. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mulligan modified by Hunt as applied to claim 18 above, and further in view of Bernstein et al. (US 20020193689).

- Regarding claim 30, Mulligan modified by Hunt doesn't teach the measuring circuit to be formed by a synchronous demodulator. However, Bernstein teaches a synchronous demodulator (40) able to extract real and imaginary impedance in order to extract impedance information from a voltage measured across a body part [0061] (Figure1). It would have been obvious in view of Bernstein to provide a synchronous demodulator

in Mulligan modified by Hunt in order to extract impedance information from a voltage measured across a body part.

5. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mulligan modified by Hunt as applied to claim 18 above, and further in view of Feldman (US 5788643).

- Regarding claim 31, Mulligan modified by Hunt doesn't teach the monitor wherein the impedance measuring unit determines a phase angle of the impedance wherein the analyzing unit analyzes the phase angle to detect congestive heart failure. However, Feldman teaches a measuring unit determining phase angle of impedance and analyzing it in the determination of chronic congestive heart failure (Figure 2). It would have been obvious in view of Feldman to provide phase angle determination capabilities in Mulligan modified by Hunt in order to determine whether to initiate intervention in cases of chronic congestive heart failure.

### ***Response to Arguments***

6. Applicant's arguments with respect to claims 18-31 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Danega whose telephone number is (571)270-3639. The examiner can normally be reached on Monday through Thursday 8:30-5:00 eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAD

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736